UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION

Mary Renee Chase, Plaintiff, v. SANOFI S.A., AVENTIS PHARMA S.A., SANOFI US SERVICES INC., and SANOFI-AVENTIS U.S. LLC, Defendants.	:	COMPLAINT AND DEMAND FOR JURY TRIAL Case No. 3:16-cv-588

COMPLAINT

Plaintiff, Mary Renee Chase ("Plaintiff"), residing in the city of Alton, Madison County, within the State of Illinois, by and through her undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Defendants Sanofi S.A., Aventis Pharma S.A., Sanofi-Aventis U.S. Services Inc., and Sanofi-Aventis U.S. LLC, ("Defendants") and alleges the following upon personal knowledge and belief, and investigation of counsel:

NATURE OF THE ACTION

1. This case involves the prescription, chemotherapy drug Taxotere, with the active ingredient docetaxel, ("Taxotere") which is manufactured, sold, distributed and promoted by Defendants for the treatment of various types of cancer, including breast cancer.

2. Taxotere can cause serious medical problems, including permanent alopecia, or hair loss. Permanent alopecia is a disfiguring condition, especially for women.

3. Defendants engaged in aggressive marketing and advertising campaigns for Taxotere that misled the consumers of Taxotere and the medical community as to the drug's safety and efficacy. As a result, consumers have suffered injuries including permanent alopecia.

PARTIES

4. Plaintiff is a natural person and a citizen of the State of Illinois and used the prescription Taxotere as prescribed and directed by her physician.

5. Defendant Sanofi S.A. is a corporation or Société Anonyme organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France. Defendants Aventis Pharma S.A., Sanofi-Aventis U.S. Services Inc., and Sanofi-Aventis U.S. LLC are wholly-owned subsidiaries of Defendant Sanofi S.A., which owns 100% of the financial and voting member interest in these Defendants.

6. Defendant Aventis Pharma S.A. is a corporation or Société Anonyme organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160, Antony, France.

7. Defendant Sanofi-Aventis U.S. Services Inc. is a Delaware corporation, which has its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendant Sanofi-Aventis U.S. Services Inc. was formerly known as Sanofi-Aventis U.S. Inc.

8. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, which has its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendant Sanofi-Aventis U.S. LLC does not have any members that are citizens, residents, or domiciles of the State of Illinois.

9. By way of background, in 1999 French company Rhône-Poulenc Rorer S.A., and its U.S. subsidiary, merged with the German corporation Hoechst Marion Roussel, and its U.S. subsidiary, to form Aventis Pharma S.A. and Aventis Pharmaceuticals in the U.S. In 2004, Sanofi-Synthelabo merged with Aventis to form Sanofi-Aventis in France and the United States. In 2011, Sanofi-Aventis S.A. changed its name to Sanofi S.A.

10. At all relevant times, Defendants acted in conjunction with other affiliated, related, jointly owned and/or controlled entities or subsidiaries, including each other, in the development, marketing, production, labeling, promoting, packaging, advertising, and/or selling of Taxotere. Defendants acted jointly and/or as each other's agents, within the course and scope of the agency, with respect to the conduct alleged in this Complaint, such that any individuality and separateness between Defendants had ceased and these Defendants became the alter-ego of one another and are jointly-liable for their misconduct and wrongful acts as alleged herein.

11. As the corporate parent of these wholly-owned subsidiaries, Sanofi S.A. directs and controls the operations of Aventis Pharma S.A., Sanofi-Aventis U.S. Services Inc., and Sanofi-Aventis U.S. LLC. Accordingly, there exists, and at all relevant times herein existed, a unity of interest, ownership, and conduct between Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC with regard to the manufacture, distribution, development, testing, and labeling of the Taxotere and other related conduct, such that any individuality and separateness between Defendants had ceased and these Defendants became the alter-ego of one another.

12. Sanofi S.A., through its various affiliates, wholly-owned subsidiaries, and predecessor companies, including Sanofi-Aventis U.S. Services Inc., Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC, has been directly involved in and has overseen the invention, development, clinical trials, and strategy for marketing, distributing, selling, and promoting Taxotere throughout the United States and the world.

13. At all times herein mentioned, Defendants, engaged in interstate commerce when they advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public the pharmaceutical product, Taxotere, in this judicial district.

JURISDICTION AND VENUE

14. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy between Plaintiff and Defendants exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

15. Venue is proper within this district pursuant to 28 U.S.C. § 1391(b)(1) because Plaintiff is a citizen and resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

DEVELOPMENT AND REGULATORY APPROVAL OF TAXOTERE

16. Chemotherapy is the use of anti-cancer drugs to treat cancer. Chemotherapy can stop the growth of a tumor, shrink the size of a tumor, kill cancer cells that have spread to other parts of the body, and decrease the chance that cancer will recur.

17. Among the family of chemotherapy drugs are Taxanes. Taxanes block cell growth by inferring with microtubules which are cellular structures that help move chromosomes during mitosis. Taxane agents include Taxotere and Taxol (paclitaxel).

18. Taxol was developed, manufactured, and distributed by Bristol-Myers Squibb. Taxol first received U.S. Food and Drug Administration ("FDA") approval in December 1992.

19. Rhône-Poulenc Rorer S.A., a predecessor of Aventis Pharma S.A., received the initial patent for the formulation and computation of Taxotere, and initially sought FDA approval for Taxotere through its U.S. representative in 1994. The FDA unanimously recommended rejecting approval of Taxotere, because Taxotere was more toxic than Taxol, and more studies of docetaxel's side effects were needed.

20. The FDA approved Taxotere on May 14, 1996 for treating locally advanced or metastatic breast cancer after when prior chemotherapy treatments failed.

21. After this initial FDA approval, the FDA granted approval for additional indications for Taxotere. In doing so, Defendants claimed superiority over other chemotherapy products approved for breast cancer treatment.

MISLEADING MARKETING OF TAXOTERE IN THE UNITED STATES

22. In marketing Taxotere, Defendants continually have made false claims of superior efficacy and omitted safety information.

False Claims of Superior Efficacy

23. On or about November 12, 2003, the FDA sent a warning letter to Aventis Pharmaceuticals North America objecting to the dissemination of three violative direct-to-consumer print advertisements for Taxotere.

24. The FDA found the advertisements misleading because "they suggest that Taxotere is more effective than has been demonstrated by substantial evidence or substantial clinical experience."

25. In its November correspondence, the FDA also noted that it had previously requested that a "Dear Doctor" letter be destroyed because it made misleading, effectiveness claims overstating the drug's survival benefits. The FDA was "particularly concerned" about the "Dear Doctor" letter.

26. In 2008, a study, *Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer*, was published in the New England Journal of Medicine. The study compared the efficacy of docetaxel (Taxotere) and paclitaxel (Taxol) in the adjuvant treatment of breast cancer.

27. The study concluded that weekly paclitaxel with doxorubicin and cyclophosphamide were more effective than docetaxel in improving disease-free and overall survival in women with breast cancer.

28. Following this study, FDA issued another letter on April 16, 2009, stating that promotional material for Taxotere again had unsubstantiated superiority claims and overstatements of efficacy.

29. Specifically, the FDA found that the promotional material "misleadingly suggest that Taxotere is superior to paclitaxel in the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy, and overstate the efficacy of Taxotere. FDA is unaware of substantial evidence to support these claims."

30. A Qui Tam lawsuit was also filed against Sanofi-Aventis U.S. Inc. and affiliated entities in the United States District Court for the Eastern District of Pennsylvania by a former employee. In the lawsuit, Sanofi-Aventis, its predecessors and its affiliates are accused of engaging in a fraudulent marketing scheme, paying kickbacks, and providing other unlawful incentives to entice doctors to use Taxotere. *See U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc., Civil Action No. 02-2964 (E.D. Pa. 2015).*

Omitted Safety Information

31. Although alopecia can be a common side effect related to chemotherapy drugs, permanent alopecia is not. Defendants, through their publications and marketing materials, misled physicians, health care professions and the public, including Plaintiff, in the United States regarding the risk of permanent alopecia.

32. In the November 2003 FDA letter referenced above, the FDA states that the advertisements for Taxotere omit and minimize the risk information. According to the FDA's

letter, the advertisements do not discuss common side effects associated with Taxotere, including hair loss.

33. On or about May 28, 2007, Defendants issued a press release touting the efficacy of Taxotere based upon a clinical study, GEICAM 9805.

34. However, Defendants failed to inform the public and health care providers that in the GEICAM 9805 study, alopecia persisted into the follow-up period (10 years and 5 months was the median follow-up time) and was observed to be ongoing in 9.2% of the patients taking Taxotere.

35. Despite Defendants' knowledge of the relevant findings from the GEICAM 9805 study, as well as reports of patients who had taken Taxotere and suffered from permanent alopecia, Defendants failed to provide accurate information and proper warnings to physicians, healthcare providers, and patients in the United States, including Plaintiff. Defendants failed to inform physicians, healthcare providers, and the public that patients who take Taxotere are at a significantly increased risk of suffering from permanent alopecia.

36. While Defendants did advise physicians, patients, and regulatory agencies in other countries, including Canada and the European Union, that Taxotere causes an increased risk of permanent alopecia, such warnings do not appear in information published by Defendants in the United States prior to December 2015.

PLAINTIFF'S TREATMENT WITH TAXOTERE AND RESULTING INJURIES

37. Plaintiff was diagnosed with breast cancer on or about January 2013.

38. Plaintiff underwent a mastectomy on or about February 2013.

39. Plaintiff underwent chemotherapy, which included Taxotere, from approximately April 2013 to August 2013. Before or during Plaintiff's treatment with Taxotere, neither

Plaintiff nor her healthcare providers were aware of or informed by Defendants that permanent alopecia can occur following treatment with Taxotere.

40. After undergoing chemotherapy with Taxotere, Plaintiff suffered from permanent alopecia as a result of receiving chemotherapy.

41. Women who experience permanent alopecia suffer great mental anguish as well as economic damages, including but not limited to loss of work or inability to work due to significant psychological damage.

42. There were already products on the market at least as effective as Taxotere that did not subject users to the same risk of permanent alopecia, but users of Taxotere were not presented with the opportunity to make an informed choice as to whether the benefits of Taxotere were worth its associated risks.

43. Defendants engaged in a pattern of deception by overstating the benefits of Taxotere as compared to other alternatives while simultaneously failing to warn of the risk of permanent alopecia.

44. As a direct result of Defendants' wrongful and deceptive acts, users of Taxotere, including Plaintiff, were exposed to the risk of permanent alopecia without any warning and without the claimed increased efficacy.

45. As a direct result of Defendants' failure to warn patients of the risk of permanent alopecia in the United States, thousands of women, including Plaintiff, as well as their health care providers, were deprived of the opportunity to make an informed decision as to whether the benefits of using Taxotere over other comparable products was justified.

46. Plaintiff files this lawsuit within two (2) years of first suspecting that the Taxotere was the cause of appreciable harm sustained by Plaintiff, within two (2) years of first suspecting

or having reason to suspect any wrongdoing, and within the applicable limitations period of first discovering their injuries and the wrongful conduct that cause such injuries. Plaintiff could not by the exercise of reasonable diligence have discovered any wrongdoing, nor could Plaintiff have discovered the causes of her injuries at an earlier time because some injuries occurred without initial perceptible trauma or harm, and when Plaintiff's injuries were discovered, their causes were not immediately known.

47. Until recently, Plaintiff did not suspect, nor did she have reason to suspect, that wrongdoing had caused her injuries. In addition, Plaintiff did not have reason to suspect the tortious nature of the conduct causing the injuries, until recently and has filed the herein action well within the applicable statute of limitations period. Plaintiff had no knowledge of the wrongful conduct of the Defendants as set forth herein, nor did Plaintiff have access to the information regarding other injuries and complaints in the possession of Defendants. Additionally, Plaintiff was prevented from discovering this information sooner because Defendant misrepresented and continue to misrepresent to the public, to the medical profession and to Plaintiff that Taxotere is safe and free from serious side effects. Defendants have fraudulently concealed facts and information that could have led Plaintiff to an earlier discovery of potential causes of action.

48. As alleged herein, as a direct, proximate, and legal result of Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to permanent alopecia. Plaintiff has endured pain and suffering, has suffered economic loss, and will continue to incur such losses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

49. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

50. Taxotere manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks. The Taxotere manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Taxotere, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

51. As a direct and proximate result of Plaintiff's reasonably anticipated use of Taxotere as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

SECOND CAUSE OF ACTION
NEGLIGENCE

52. Plaintiff incorporates by reference each of the allegations set forth in this Complaint as though set forth herein.

53. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute,

market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Taxotere.

54. At all times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Taxotere and failed to adequately test and warn of the risks and dangers of Taxotere.

55. Despite the fact that Defendants knew or should have known that Taxotere caused unreasonable, dangerous side effects, Defendants continued to market Taxotere to consumers including Plaintiff, when there were safer alternative chemotherapy treatments available, which were just as effective.

56. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

57. Defendants' negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

THIRD CAUSE OF ACTION
FRAUD

58. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

59. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Taxotere, and up to the present, willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning Taxotere, which the Defendants had a duty to disclose.

60. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Taxotere and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Taxotere. Defendants knew of the foregoing, that using Taxotere is hazardous to health, that Taxotere is not more effective than safer alternatives available, and that Taxotere has a propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

61. Defendants concealed and suppressed the true facts concerning Taxotere with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff's physicians would not prescribe Taxotere, and Plaintiff would not have used Taxotere, if they were aware of the true facts concerning its dangers.

62. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION – PUNITIVE DAMAGES

63. Plaintiff incorporates by reference each of the allegations set forth in this Complaint as though fully set forth herein.

64. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint, were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other Taxotere users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Taxotere. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

65. Prior to the manufacturing, sale, and distribution of Taxotere, Defendants knew that said medication was in a defective condition as previously described herein and knew that

those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of serious and permanent injury from using Taxotere.

66. Despite their knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Taxotere and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Taxotere. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Taxotere knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

67. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

A. For general damages in a sum in excess of the jurisdictional minimum of this Court;

B. Medical expenses, past and future, according to proof at the time of trial;

C. For past and future mental and emotional distress, according to proof;

D. For punitive or exemplary damages according to proof;

E. For pre-judgment and post-judgment interest as provided by law;

F. Restitution, disgorgement of profits, and other equitable relief;

G. For attorneys' fees, expenses, and costs of this action; and

H. For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: May 27, 2016

Respectfully submitted,

/s/ Trent B. Miracle

Trent B. Miracle
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Phone: (618) 259-2222
Fax: (618) 259-2252
Email: tmiracle@simmonsfirm.com

Timothy J. Becker, Esq. (MN #256663)
Michael K. Johnson (MN Bar # 258696)
Peter C. Snowdon (MN Bar # 389642)
Johnson Becker, PLLC
33 South 6th Street, Suite 4530
Minneapolis, MN 55402
Telephone: 612-436-1800
Fax: 612-436-1801
Email: tbecker@johnsonbecker.com
mjohnson@johnsonbecker.com
psnowdon@johnsonbecker.com

Attorneys for Plaintiff